

FORM PTO-1449

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Atty Docket No.

P1085R4-1A

Serial No.

09/234,182

LIST OF DISCLOSURES CITED BY APPLICANT

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Applicant

Hsei et al.

Filing Date

20 Jan 1999

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1643

U.S. PATENT DOCUMENTS

Examiner Initials		Document Number	Date	Name	Class	Subclass	Filing Date
	1	4,002,531	11.01.77	Royer			
	2	4,179,337	18.12.79	Davis et al.			
	3	4,732,863	22.03.88	Tomasi et al.			
	4	5,147,537	15.09.92	Sada et al.			
	5	5,166,322	24.11.92	Shaw et al.			
	6	5,169,627	08.12.92	Cunningham-Rundles			
	7	5,527,528	18.06.96	Allen et al.			
	8	5,532,150	02.07.96	Snow et al.			
	9	5,595,732	21.01.97	Hakini et al.			
	10	5,620,689	15.04.97	Allen et al.			
	11	5,643,575	01.07.97	Martinez et al.			
	12	5,661,020	26.08.97	Snow et al.			
	13	5,670,132	23.09.97	Griffiths et al.			
	14	5,677,426	14.10.97	Fong et al.			
	15	5,686,070	11.11.97	Doerschuk et al.			
	16	5,695,760	09.12.97	Faanes et al.			
	17	5,698,196	16.12.97	Matsushima et al.			
	18	5,702,946	30.12.97	Doerschuk et al.			
	19	5,707,622	13.01.98	Fong et al.			
	20	5,766,897	16.06.98	Braxton, S.			

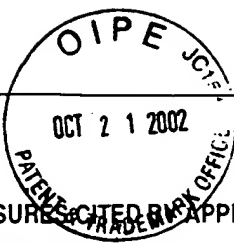
FOREIGN PATENT DOCUMENTS

Examiner Initials		Document Number	Date	Country	Class	Subclass	Translation Yes No	
	21	770,628	02.05.97	EPO ✓				
	22	WO 92/04372	19.03.92	PCT ✓				
	23	WO 94/12219	09.06.94	PCT ✓				
	24	WO 94/21235	29.09.94	PCT				
	25	WO 95/11987	04.05.95	PCT ✓				
	26	WO 95/15769	15.06.95	PCT ✓				
	27	WO 95/23813	08.09.95	PCT ✓				
	28	WO 95/23865	08.09.95	PCT ✓				
	29	WO 95/32003	30.11.95	PCT ✓				
	30	WO 96/02576	01.02.96	PCT ✓				
	31	WO 96/09325	28.03.96	PCT ✓				
	32	WO 96/34015	31.10.96	PCT ✓				
	33	WO 96/40731	19.12.96	PCT ✓				

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	34	WO 97/10847	27.03.97	PCT				
	35	WO 98/25971	18.06.98	PCT				
	36	WO 98/37200	27.08.98	PCT				
	37	WO 99/37779	29.07.99	PCT				

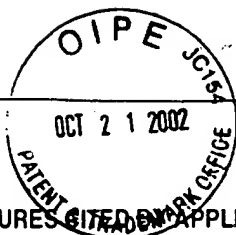
OTHER DISCLOSURES (Including Author, Title, Date, Pertinent Pages, etc.)

	38	Abuchowski and Davis, "Soluble Polymer- Enzyme Adducts" <u>Enzymes as Drugs</u> , Holcenberg, JS; Roberts, J eds., New York: Wiley, Chapter 13, pps. 367-383 (1981)
	39	Adagen Label <u>Physicians' Desk Reference</u> (Product Information), 48 edition, Montvale, NJ: Medical Economics Data Production Company pps. 917-918 (1994)
	40	Allen et al., "A new strategy for attachment of antibodies to sterically stabilized liposomes resulting in efficient targeting to cancer cells" <u>Biochimica et Biophysica Acta</u> 1237(2):99-108 (Jul 26, 1995)
	41	Anderson and Tomasi, "Polymer modification of antibody to eliminate immune complex and Fc binding" <u>Journal of Immunological Methods</u> 109(1):37-42 (Apr 22, 1988)
	42	Beauchamp et al., "A new procedure for the synthesis of polyethylene glycol-protein adducts; effects on function, receptor recognition, and clearance of superoxide dismutase, lactoferrin, and α_2 -macroglobulin" <u>Analytical Biochemistry</u> 131(1):25-33 (1983)
	43	Brooks and Stocks, "Use of polyacrylamide-derivatized antibody in dextran-poly(ethylene glycol) systems" <u>Methods in Enzymology</u> 228:390-395 (1994)
	44	Brumeanu et al., "Derivatization with monomethoxypolyethylene glycol of Igs expressing viral epitopes obviates adjuvant requirements" <u>Journal of Immunology</u> 154(7):3088-3095 (Apr 1, 1995)
	45	Carter et al., "Preparation and uses of Fab' fragments from Escherichia coli" <u>Antibody Engineering: a Practical Approach</u> , Hoogenboom, H., McCafferty, J., Chiswell, D. eds., Oxford, UK: IRL Press, Chapter 13, pps. 291-308 (1996)
	46	Chamow et al., "Modification of CD4 immunoadhesin with monomethoxypoly(ethylene glycol) aldehyde via reductive alkylation" <u>Bioconjugate Chemistry</u> 5(2):133-140 (Mar-Apr 1994)
	47	Chapman et al., "Therapeutic antibody fragments with prolonged in vivo half-lives" <u>Nature Biotechnology</u> 17(8):780-783 (Aug 1999)
	48	Clark et al., "Long-acting growth hormones produced by conjugation with polyethylene glycol" <u>Journal of Biological Chemistry</u> 271(36):21969-21977 (Sep. 6, 1996)
	49	Cunningham-Rundles et al., "Biological activities of polyethylene-glycol immunoglobulin conjugates. Resistance to enzymatic degradation" <u>Journal of Immunological Methods</u> 152(2):177-190 (Aug 10, 1992)
	50	Davis et al., "Soluble, Nonantigenic Polyethylene Glycol-Bound Enzymes" <u>Biomedical Polymers: Polymeric Materials and Pharmaceuticals for Biomedical Use</u> , Goldberg, E and Nakajima, A eds., New York: Academic Press pps. 441-452 (1980)
	51	Delgado et al., "Analytical partitioning of poly(ethylene glycol)-modified proteins" <u>Journal of Chromatography B</u> 692(2):263-272 (May 9, 1997)
	52	Delgado et al., "Distinct Influence of PEGylation on the Tumour Localisation of Transferrin and a Tumour-Specific Fab Fragment (F9)" <u>Journal of Cellular Biochemistry</u> (Abstr. A4-101, Keystone Symposium held at Hilton Head Island, SC, Jan 7-13 1995) Suppl. 19A:171 (1995)
	53	Delgado et al., "Enhanced tumour specificity of an anti-carcinoembryonic antigen Fab' fragment by poly(ethylene glycol) (PEG) modification" <u>British Journal of Cancer</u> 73(2):175-182 (Jan 1996)

Examiner

Date Considered

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Group

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OTHER DISCLOSURES (Including Author, Title, Date, Pertinent Pages, etc.)

54	Delgado et al., "The uses and properties of PEG-linked proteins" <u>Critical Reviews in Therapeutic Drug Carrier Systems</u> 9(3-4):249-304 (1992)
55	Deuel et al., "Amino acid sequence of human platelet factor 4" <u>Proc. Natl. Acad. Sci.</u> 74:2256-2258 (1977)
56	Elling and Kula, "Immunoaffinity partitioning: synthesis and use of polyethylene glycol-oxirane for coupling to bovine serum albumin and monoclonal antibodies" <u>Biotechnology and Applied Biochemistry</u> 13(3):354-362 (Jun 1991)
57	Eno-Amooquaye et al., "Altered biodistribution of an antibody-enzyme conjugate modified with polyethylene glycol" <u>British Journal of Cancer</u> 73(11):1323-1327 (Jun 1996)
58	Gonzalez et al., "Humanization of Murine 6G425: An Anti-IL8 Monoclonal Antibody Which Blocks Binding of IL8 to Human Neutrophils" <u>1996 Keystone Symposia on Exploring and Exploiting Antibody and Ig Superfamily Combining Sites</u> (Poster) pps. 1-21 (February 1996)
59	Harding et al., "Immunogenicity and pharmacokinetic attributes of poly(ethylene glycol)-grafted immunoliposomes" <u>Biochimica et Biophysica Acta</u> 1327(2):181-192 (Jul 25, 1997)
60	Harris et al., "Synthesis and Characterization of Poly(ethylene Glycol) Derivatives" <u>J. Polym. Sci., Polym. Chem. Ed.</u> 22(2):341-352 (1984)
61	Haselgrubler et al., "Synthesis and applications of a new poly(ethylene glycol) derivative for the crosslinking of amines with thiols" <u>Bioconjugate Chemistry</u> 6(3):242-248 (May-Jun 1995)
62	Hebert et al., "Endothelial and Leukocyte Forms of IL-8: Conversion by Thrombin and Interactions with Neutrophils" <u>J. Immunol.</u> 145(9):3033-3040 (Nov 1, 1990)
63	Hebert et al., "Interleukin-8: A Review" <u>Cancer Investigation</u> 11(6):743-750 (1993)
64	Karr et al., "Use of poly(ethylene glycol)-modified antibody in cell extraction" <u>Methods in Enzymology</u> 228:377-390 (1994)
65	Katre N., "The Conjugation of Proteins with Polyethylene Glycol and other Polymers. Altering properties of proteins to enhance their therapeutic potential." <u>Advanced Drug Delivery Reviews</u> 10(1):91-114 (1993)
66	Kawamura et al., "Immune responses to polyethylene glycol modified L-asparaginase in mice" <u>International Archives of Allergy & Applied Immunology</u> 76(4):324-330 (1985)
67	Kirpotin et al., "Sterically stabilized anti-HER2 immunoliposomes: design and targeting to human breast cancer cells in vitro" <u>Biochemistry</u> 36(1):66-75 (Jan 7, 1997)
68	Kitamura et al., "Chemical engineering of the monoclonal antibody A7 by polyethylene glycol for targeting cancer chemotherapy" <u>Cancer Research</u> 51(16):4310-4315 (Aug 15, 1991)
69	Kitamura et al., "Polyethylene glycol modification of the monoclonal antibody A7 enhances its tumor localization" <u>Biochemical & Biophysical Research Communications</u> 171(3):1387-1394 (Sep 28, 1990)
70	Knauf et al., "Relationship of Effective Molecular Size to Systemic Clearance in Rats of Recombinant Interleukin-2 Chemically Modified with Water Soluble Polymers" <u>The Journal of Biological Chemistry</u> 263(29):15064-15070 (Oct 15, 1988)
71	Ko et al., "A sensitive enzyme-linked immunosorbent assay for human interleukin-8" <u>J. Immunol. Methods</u> 149:227-235 (1992)
72	Koumenis et al., "Tailoring antibody fragments with PEGylation without loss in biological activity" <u>Protein Science</u> (Abstract 109-M, presented at the Protein Society's Twelfth Symposium in San Diego, CA on July 25-29, 1998) 7(Suppl. 1):73 (Jul 1998)
73	Lang et al., "Suppression of antibody responses in rats to murine anti-CD4 monoclonal antibodies by conjugates with monomethoxypolyethylene glycol" <u>Immunology Letters</u> 32(3):247-252 (May 1992)

Examiner

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74	Lee and Sehon, "Suppression of reaginic antibodies with modified allergens. I. Reduction in allergenicity of protein allergens by conjugation to polyethylene glycol" <u>International Archives of Allergy & Applied Immunology</u> 56(2):159-170 (1978)
75	Mainolfi, E. et al., "Reduction of Immunogenicity of A Murine ANTI-ICAM-1 Antibody Through Pegylation Chemistry" <u>The 9th International Congress of Immunology (abstract book)</u> (abstract #5247) pps. 885 (1995)
76	Maiti et al., "Tolerogenic conjugates of xenogeneic monoclonal antibodies with monomethoxypolyethylene glycol. I. Induction of long-lasting tolerance to xenogeneic monoclonal antibodies" <u>International Journal of Cancer Suppl.</u> 3:17-22 (1988)
77	Maruyama et al., "Immunoliposomes bearing polyethyleneglycol-coupled Fab' fragment show prolonged circulation time and high extravasation into targeted solid tumors in vivo" <u>FEBS Letters</u> 413(1):177-180 (Aug 11, 1997)
78	Maruyama et al., "Targeting efficiency of PEG-immunoliposome-conjugated antibodies at PEG terminals" <u>Advanced Drug Delivery Reviews</u> 24:235-242 (1997)
79	Mulligan et al., "Inhibition of Lung Inflammatory Reactions in Rats by an Anti-Human IL-8 Antibody" <u>J. Immunol.</u> 150(12):5585-5595 (June 15, 1993)
80	Nordvall et al., "IgG and IgE antibody patterns after immunotherapy with monomethoxy polyethyleneglycol modified honey bee venom" <u>Allergy: European Journal of Allergy & Clinical Immunology</u> 41(2):89-94 (Feb 1986)
81	Pedley et al., "The potential for enhanced tumour localisation by poly(ethylene glycol) modification of anti-CEA antibody" <u>British Journal of Cancer</u> 70(6):1126-1130 (Dec 1994)
82	Sekido et al., "Prevention of lung reperfusion injury in rabbits by a monoclonal antibody against interleukin-8" <u>Nature</u> 365:654-657 (October 14, 1993)
83	Shahinian and Silviu, "A novel strategy affords high-yield coupling of antibody Fab' fragments to liposomes" <u>Biochimica et Biophysica Acta</u> 1239(2):157-167 (Nov 1, 1995)
84	Sharp et al., "Synthesis and application of a poly(ethylene glycol)-antibody affinity ligand for cell separations in aqueous polymer two-phase systems" <u>Analytical Biochemistry</u> 154(1):110-117 (Apr 1986)
85	(Shearwater Polymers, Inc.'s January 1996 Catalog of Polyethylene Glycol Derivatives) pps. 1-50
86	St. John et al., "Immunologic Therapy for ARDS, Septic Shock, and Multiple-Organ Failure" <u>Chest</u> 103:932-943 (1993)
87	Sticherling et al., "Immunohistochemical studies on NAP-1/IL-8 in contact eczema and atopic dermatitis" <u>Arch. Dermatol. Res.</u> 284:82-85 (1992)
88	Sticherling et al., "Production and Characterization of Monoclonal Antibodies Against the Novel Neutrophil Activating Peptide NAP/IL-8" <u>J. Immunol.</u> 143(5):1628-1634 (September 1, 1989)
89	Suzuki et al., "Physicochemical and biological properties of poly(ethylene glycol)-coupled immunoglobulin G. Part II. Effect of molecular weight of poly(ethylene glycol)" <u>Journal of Biomaterials Science, Polymer Edition</u> 1(2):71-84 (1989)
90	Suzuki et al., "Preparation and characteristics of magnetite-labelled antibody with the use of poly(ethylene glycol) derivatives" <u>Biotechnology & Applied Biochemistry</u> 21(Pt 3):335-345 (Jun 1995)
91	Tanaka et al., "Synthesis and biological characterization of monocyte-derived neutrophil chemotactic factor" <u>FEBS Letters</u> 236(2):467-470 (Aug 1988)
92	Van Damme et al., "Purification of granulocyte chemotactic peptide/interleukin-8 reveals N-terminal sequence heterogeneity similar to that of β -thromboglobulin" <u>European Journal of Biochemistry</u> 181:337-344 (1989)
93	Veronese et al., "Improvement of pharmacokinetic, immunological and stability properties of asparaginase by conjugation to linear and branched monomethoxy poly(ethylene glycol)" <u>Journal of Controlled Release</u> 40:199-209 (1996)

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- | | |
|----|---|
| 94 | Wie et al., "Suppression of reagenic antibodies with modified allergens. III. Preparation of tolerogenic conjugates of common allergens with monomethoxypolyethylene glycols of different molecular weights by the mixed anhydride method" <u>International Archives of Allergy & Applied Immunology</u> 64(1):84-99 (1981) |
| 95 | Yoshimoto et al., "Chemical modification of tryptophanase from E. coli with polyethylene glycol to reduce its immunoreactivity towards anti-tryptophanase antibodies" <u>Enzyme</u> 36(4):261-265 (1986) |
| 96 | Yoshimura et al., "Neutrophil attractant/activation protein-1 and monocyte chemoattractant protein-1 in rabbit. cDNA cloning and their expression in spleen cells" <u>J. Immunol.</u> 146:3483-3488 (1991) |
| 97 | Zapata et al., "Site-Specific Coupling of Monomethoxypoly(ethylene glycol) to a Single-Sulphydryl Humanized Fab" (poster presented at the American Society for Biochemistry and Molecular Biology FASEB Meeting in San Francisco, CA on May 21-25, 1995) pps. 1-27 |
| 98 | Zapata et al., "Site-Specific Coupling of Monomethoxypoly(ethylene glycol) to a Single-Sulphydryl Humanized Fab" <u>FASEB Journal</u> (Abstract #1288, presented at the American Society for Biochemistry and Molecular Biology FASEB Meeting in San Francisco, CA on May 21-25, 1995) 9(6):A1479 (1995) |

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